Published by Ministry of Health, Labour and Welfare



Translated by Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Dulaglutide (genetical recombination)

May 30, 2017

Non-proprietary name

Dulaglutide (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Anaphylaxis, angioedema:

Anaphylaxis, or angioedema may occur. Patients should be carefully monitored. If any abnormalities including urticaria, lip swelling, pharyngeal/laryngeal oedema, and dyspnoea are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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